

93/16175. Claims 1-6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Edwards, Jr., in view of WO 93/16175, Bedford (U.S. Patent No. 5,612,055), Lyons (Proc. Alltech's 8th Annual Symp.) or CN 1135297 for the reasons noted. This rejection is respectfully traversed.

Initially, however, Applicants note the Examiner's indication that claims 1-3 would be allowable if claim 1 was amended to recite that the animal suffers from mastitis. Applicants have amended claim 1 accordingly. Therefore, claims 1-3, and new claims 7-8 are in allowable condition. The Examiner's assistance and cooperation in expediting the prosecution of this application is gratefully acknowledged.

Regarding new claims 9-13, such recite a method of preventing mastitis in females ruminants by administering a therapeutically effective amount of phytase in feed. By providing sufficient phytase as feed to a healthy ruminant, as described in Table 7, Example 7 at specification pages 14-15, prevention of mastitis is plainly demonstrated. This is not suggested in the prior art and, in fact, is taught away from by the references cited. At the least, respectfully submitted, such is neither taught nor suggested by the prior art, as discussed below in more detail.

In the Office Action, the Examiner states

"It is noted that the claims [claims 1-6] are drawn to administering phytase to a mammal and that the mammal is not defined as suffering from mastitis."

In partial response, applicants' claim 9 has been presented, as noted, to utilize language reciting that the animal is a "female ruminant" and thus the claim is directed to a method for preventing mastitis by administering a therapeutic amount of phytase to the female ruminants.

Edward teaches administering phytase to animals. However, Edward does not teach administration of phytase to ruminants. Rather, although Edwards mentions

cattle (column 6, line 40), the reference is particularly directed towards treatment of fowl. In any event, Edward relates to prevention of tibial dyschondroplasia and not to prevention of mastitis, least of all to prevention of mastitis in female ruminants.

WO 93/16175 merely discloses "feed preparations for monogastric animals", and contains no disclosure of administering of phytase to ruminants.

Bedford, frankly speaking, is thought to be the closest prior art. Bedford is cited as being relevant for disclosing the administration of a feed comprising enzymes such as phytase to animals such as cows. However, Bedford's invention relates to "an enzyme feed additive comprising a xylanase, a protease and optionally a β -glucanase". In column 8, lines 16-19, as pointed out by the Examiner, there is a list of other enzymes that may be included. Bedford merely includes phytase in that laundry list, but contains no disclosure relating to the administration of phytase to a ruminant, let alone administering in the form of feed an effective amount of phytase to prevent mastitis in a female ruminant.

Even considering the Examples in Bedford, there is simply no instance wherein phytase is added. That is, in Example 1 feed is given to "Cobb male broiler chickens", in Example 2, to "Ross 1 broiler chickens", in Example 3, to "Ross 1 male broiler chickens", in Example 4, to "male pigs", in Example 5, to "Turkey poults".

Moreover, at column 16, lines 22-25, Bedford describes that feed conversion ratio can be increased by providing the "feed in accordance with the present invention to animals such as geese, ducks, sheep and cows, as well as to chickens, turkeys and pigs." Suffice it to say, however, there are no examples of determining FCR values for cows and sheep.

This is, in fact, expected since it is well-known that microorganisms in the ruminant stomach produce phytase and the ruminants themselves are able to break down phytic acid. In other words, since there is no need to provide phytase, phytase would never

*
Col. 8, lines
16-19
Phytase only
not for ruminants
disclosure.
see col.
10 lines
37-40.

be added to ruminant feed. See from specification page 2, line 23 - page 3, line 1. Therein lies the nature of Applicants' discovery.

On page 7 of Lyon, "Pollution of Waterways: A role for the Enzyme Phytase", from line 3 of the second complete paragraph discusses:

"Monogastrics, however, lack the enzyme phytase which is required to release the organically bound phosphorus and a considerable quantity of inorganic phosphorous must therefore be added to pig and poultry feeds."

As understood by those of ordinary skill, this plainly means that phytase which is added to animal feed according to the reference is for use in monogastric animals such as pigs and poultry which cannot produce phytase by themselves, and not to ruminants.

Finally, CN 1135297 is directed to a "Feed additive for bull-frog cultivation containing zinc methionine sulphate". The document relates to feed for frogs and contains no disclosure related to the administration of phytase to ruminants.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-3 and 7-13 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Lawrence S. Perry", is written over a horizontal line.

Attorney for Applicants
Lawrence S. Perry
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

1. (Amended) A method [for preventing and] treating mastitis in mammals excluding humans, which comprises administering phytase to [the] mammals that suffer from mastitis.

2. (Amended) The method for [preventing and] treating mastitis in mammals [excluding humans] of claim 1, which comprises administering feedstuff containing [phytase] 50 to 5,000 units phytase per kg of [the] dry feed matter.

3. (Amended) The method for [preventing and] treating mastitis of claim 1, wherein the mammal is a cow and the feedstuff is formula feed for dairy cows.

4. (Canceled)

5. (Canceled)

6. (Canceled)